MEDICAL MUTUAL®

Drug Policy

Policy:	Hydroxyurea Products • **Siklos (hydroxyurea tablets – Addmedica/Medunik)** • **Xromi (hydroxyurea oral solution – Nova Laboratories)**	**Annual Review Date:** **06/20/2024** **Last Revised Date:** **06/20/2024**

OVERVIEW

Sickle cell disease (SCD), a multisystem disorder, is the most common condition caused by a single gene mutation. SCD is characterized by the presence of abnormal erythrocytes damaged by the sickle hemoglobin (HbS) gene. This variant of the normal adult hemoglobin (HbA) can be inherited from both parents or from one parent along with another variant, such as hemoglobin C (HbC) or with β-thalassemia. SCD can lead to pain crises when sickle cells block blood flow and decrease oxygen delivery; pain episodes can be acute or chronic. Other complications associated with SCD include severe anemia, brain complications (e.g., stroke), heart disease, pulmonary hypertension, kidney and liver complications, joint complications, gallstones, and infections.

POLICY STATEMENT

This policy involves the use of Siklos and Xromi. Prior authorization is recommended for pharmacy benefit coverage of Siklos and Xromi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Siklos and Xromi is recommended in those who meet the following criteria:

1. <u>Sickle Cell Anemia</u>

Criteria. *Patient must meet the following criteria (A, B, C, D, <u>and</u> E):*

A. The product is used to reduce the frequency of painful crises; AND
B. The product is being used to reduce the need for blood transfusions; AND
C. The patient experiences recurrent, moderate to severe painful crises; AND
D. The patient meets one of the following (a <u>*or*</u> b):
    a. The 100 mg or 1,000 mg tablets are required to achieve a dosage that cannot be achieved with other available formulations of hydroxyurea (e.g. Droxia capsules); OR
    b. The patient cannot swallow or has difficulty swallowing.
E. The patient meets one of the following (a <u>*or*</u> b):

a. For Siklos requests the patient is 2 years of age or older; OR
b. For Xromi requests the patient is aged 6 months to less than 2 years of age.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Siklos and Xromi have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Hydroxyurea. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 8 December 2022. Accessed on 21 February 2023.
2. Siklos® tablets [prescribing information]. Bryn Mawr, PA: Medunik USA Inc; November 2023.
3. Xromi oral solution [prescribing information]. Leicester, UK: Nova Laboratories Ltd; April 2024.